

Mail Stop: SEQUENCE

PATENT 0508-1167

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#### IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

ALVES et al.

Conf. 2683

Application No. 10/586,348

Group .

Filed July 14, 2006

Examiner

METHOD FOR OVERPRODUCING A SPECIFIC RECOMBINANT PROTEIN WITH P. CINNABARINUS MONOKARYOTIC STRAINS

# RESPONSE TO DECISION ON PETITION UNDER 37 C.F.R. § 1.181

Assistant Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

July 28, 2008

Sir:

In response the Decision on Petition dated July 17, 2008, Applicants respond as follows:

Remarks begin on page 3 of this paper.

An **Appendix** is attached following the signature page of this paper.

# In the Sequence Listing:

Please insert the attached Sequence Listing in computer readable form (CRF) of the initial paper copy of the Sequence Listing into the file at the end of the specification.

#### REMARKS

Applicants thank Ms. Graysay for taking the time to discuss the above-identified application with the undersigned.

Responsive to the Decision regarding the PTO's response to the "Response to Notification of Defective Response" filed 28 May 2008, which has been treated as a petition under 37 C.F.R. § 1.181 dated July 17, 2008, Applicants respectfully submit a computer readable form (CRF) of the initial paper copy of the Sequence Listing and hereby state that the attached computer readable form (CRF) is identical to the initial paper copy of the Sequence Listing, in accordance with 37 C.F.R. § 1.821. No new matter has been added. A copy of the Decision on Petition is attached herewith.

In view of the foregoing, it is believed that each requirement set forth in the Decision on Petition has been satisfied, and that the application is now in compliance with the Sequence Rules under 37 C.F.R. § 1.821.

Favorable action on the merits is respectfully requested.

The commissioner is hereby authorized in this, concurrent, and future submissions, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,
YOUNG & THOMPSON

Robert A. Madsen, Reg. 58,543

209 Madison Street Suite 500

Alexandria, VA 22314 Telephone (703) 521-2297

Telefax (703) 685-0573 (703) 979-4709

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# APPENDIX:

The Appendix includes the following item(s):

□ Sequence Listing in computer readable form (CRF) of the initial paper copy of the Sequence Listing

□ Copy of the Decision on Petition under 37 C.F.R. 1.181
 dated July 17, 2008

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United States Patent and Trademark Office

Commissioner for Patents

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P.O. Box 1450

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YOUNG & THOMPSON 745 South 23rd Street Second Floor Arlington, Virginia 22202

In re Application of: ALVES et al. U.S. Application No.: 10/586348

PCT Application No.: PCT/FR2005/000093 International Filing Date: 14 January 2005 Priority Date Claimed: 15 January 2004

Attorney Docket No.: 0508-1167

For: METHOD FOR OVERPRODUCING A SPECIFIC RECOMBINANT PROTEIN WITH P.CINNABARINUS

MONOKARYOTIC STRAINS

DECISION ON PETITION

This communication is responsive to the "Response to Notification of Defective Response" filed 28 May 2008, which has been treated as a petition under 37 CFR 1.181.

## **BACKGROUND**

On 14 July 2006, applicant submitted national phase papers in the United States Designated/Elected Office (DO/EO/US). The papers provided PCT/FR2005/000093 as the international application number.

On 19 September 2007, the DO/EO/US mailed a Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US), which indicates the following:

- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. And requires, inter alia, an initial paper copy of the sequence listing.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- Substitute drawings in compliance with 37 CFR 1.84 because drawing figures contain text that is not in English (including, for example, a flow chart that was originally not in English that has been marked up to include the English text) see 37 CFR 1.84(p)(2) and 37 CFR 1.52(d)(1).

On 22 January 2008 applicant filed a response which includes:

a copy of the sequence listing in computer readable form

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- a paper copy of the sequence listing that consists of twenty-six (26) pages containing a list of eighteen (18) sequences ("twenty-six (26) page paper copy")
- a statement that the attached paper and computer readable copies have the same content, and introduce no new matter into the present application
- an instruction to enter the sequence listing into the application, and
- thirteen (13) sheets of substitute drawings (Figs. 1-12) in compliance with 37 CFR 1.84.

On 25 January 2008, the DO/EO/US mailed a first *Notification of Defective Response*, which indicates the application clearly fails to comply with the requirements of 37 CFR 1.821-1.825 and requires, *inter alia*, an <u>initial</u> paper copy of the sequence listing.

On 25 February 2008, applicant filed a response which alleged that the DO/EO/US had not acknowledged the 22 January 2008 response. In support, applicant provided a complete copy of the 22 January 2008 response and requested that the 22 January 2008 response be considered.

On 28 April 2008, the DO/EO/US mailed a second *Notification of Defective Response*, which indicates the following:

- Applicant's response was filed 10/17/2006.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content does not comply with 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written sequence listing and, where applicable, includes no new matter.

On 28 May 2008, applicant filed a response which alleged that the marked-up "Raw Sequence Listing" was not received; however, applicant indicated that the response was prepared after reviewing the marked-up document using the Patent Application Information Retrieval (PAIR) system.

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## **DISCUSSION**

Upon investigation, the record reveals that a paper copy of the sequence listing was provided to the DO/EO/US by the International Bureau. In accordance with 37 CFR 1.821(c), the initial submission of the international application contained disclosures of sequences and contained, as a separate part of the disclosure, a paper copy of the sequence listing which consists of twenty-three (23) sheets containing a listing of sixteen sequences ("initial paper copy"). Thus, the requirement that applicant provide an initial paper copy of the sequence listing made in the 19 September 2007 Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) was in error insofar as the initial paper copy of the sequence listing was received from the International Bureau.

The 25 January 2008 Notification of Defective Response is hereby VACATED because it was mailed prematurely, i.e., before the validation report for the 22 January 2008 computer readable form was completed.

In accordance with 37 CFR 1.821(e) the initial paper copy of the sequence listing must also be submitted in computer readable form that is in compliance with 37 CFR 1.824. In accordance with 37 CFR 1.821(f) a statement that the paper copy and the computer readable copy are the same must be submitted with the computer readable form. Applicant has not submitted a computer readable form of the initial paper copy of the sequence listing or a statement that the sequence listing information recorded in computer readable form is identical to the initial paper copy of the sequence listing. The computer readable form and statement submitted by applicant on 22 January 2008 are not submitted with regard to the initial paper copy, but instead refer to the twenty-six (26) page paper copy.

For reasons above, the copy of the sequence listing in computer readable form, the twenty-six (26) page paper copy of the sequence listing, and the statement received 22 January 2008 fail to comply with 37 CFR 1.821(e) and are not a proper response to the 19 September 2007 Notification of Corrected Papers under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US).

As a separate issue, the copy of the sequence listing in computer readable form submitted by applicant on 22 January 2008, when treated as a preliminary amendment, remains deficient because the computer readable form of the 22 January 2008 sequence listing contains errors (see attached 06 February 2008 validation/error report). Should applicant choose to submit a substitute computer readable form of the twenty-six (26) page paper copy of the sequence listing, the substitute computer readable form should be clearly distinguished from the computer readable form of the initial paper copy and the requisite statement should clearly identify the substitute computer readable form and relevant paper copy of the sequence listing.

# **CONCLUSION**

The petition is **GRANTED to the extent** that the DO/EO/US has not previously notified applicant that a computer readable form of the initial paper copy of the sequence listing has not been received and that there is an inconsistency among the initial paper copy of the sequence listing, the computer readable form, and the twenty-six (26) page paper copy of the sequence listing.

Applicant is given **ONE** (1) **MONTH** from the mail date of this decision to provide a computer readable form of the initial paper copy of the sequence listing and a statement that the sequence listing information recorded in the computer readable form is identical to the initial paper copy of the sequence listing, in accordance with 37 CFR 1.821. Extensions of time may not be obtained under 37 CFR 1.136(a).

Correspondence with respect to this matter should be addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

Tamara Graysay

PCT Special Program Examiner
Office of PCT Legal Administration

Telephone: (571) 272-6728

Facsimile: (571) 273-0459

Brantin

Bryan Lin
PCT Legal Examiner

Office of PCT Legal Administration

Attachment: Validation/Error Report (regarding 22 January 2008 CRF), 11 pages